REMARKS

Reconsideration and withdrawal of the rejections set forth in the Office action dated November 21, 2002 are respectfully requested.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page(s) is/are captioned **"Version With Markings to Show Changes Made."**

I. Amendments

A. In the Specification:

The specification is amended to perfect the claim to priority by correctly setting forth the relationship of the prior applications.

The specification is further amended to correct typographical errors.

B. In the Claims:

Claim 63 stands cancelled.

Claims 53 and 57 are amended to recite that the electrodes are pre-shaped to assume a curved shape when deployed. Support for this amendment can be found on page 9, lines 7-9, page 12, lines 4-7, and in Figure 3.

Claim 53 is further amended to recite that the advancing step is effective to place the distal end of the delivery device in or adjacent the tumorous tissue. Support for this amendment can be found on page 13, line 7 and lines 20-23.

Claim 53 is further amended to recite that the delivery of energy is regulated in response to the temperature. Support for this amendment can be found on page 11, lines 8-11.

Claim 57 is further amended to recite that the ablation apparatus includes an elongated delivery device. Support for this amendment can be found in claim 53.

Claim 57 is further amended to recite a characteristic that is monitored. Support for this amendment can be found on page 14, lines 25-28.

Claim 57 is further amended to recite "at least one sensor." Support for this amendment can be found on page 10, lines 18-19.

Claim 57 is further amended to recite that the delivery of energy is regulated in response to the characteristic. Support for this amendment can be found on page 11, lines 8-11.

Claim 60 is amended to depend from claim 57.

Claim 64 is amended to clarify that the electrode lumen is "capable of being operatively coupled to an infusion source" and that the method includes infusing a lumen through the electrode into the tissue. Support for these amendments can be found on page 14, lines 4-8.

The claims have further been amended for conformation of language.

New claims 67-73 find support in the table below.

Claim No.	Support
67	See page 67, lines 5-8 and page 68, lines 8-11 and original claim 1
68	See page 67, lines 5-8 and page 68, lines 8-11
69	See page 9, lines 18-19
70	See page 9, lines 19-21
71	See page 11, lines 3-4
72	See page 11, lines 3-4
73	See page 16, lines 4-5

By these amendments, no new subject matter has been added.

II. Priority Claim

In the Amendment mailed February 13, 2002, Applicants included a request to withdraw the claim of priority to U.S. Patent No. 5,536,267. This request was in error and Applicants respectfully request to re-establish the claim to priority to at least the '267 patent. Applicants have amended the inventorship accordingly. Applicants have additionally amended the first paragraph of the application to correctly set forth the relationship of the prior applications.

Accordingly, Applicants submit that they have complied with all of the conditions for receiving the benefit of an earlier filing date under 35 U.S.C. §120.

III. Request to Correct Inventorship Under 37 C.F.R. § 1.48(a)

Applicants hereby submit a Request to Correct Inventorship under 37 C.F.R. § 1.48(a) to add Stuart D. Edwards as a co-inventor of the invention set forth in the pending claims.

IV. Rejection under 35 U.S.C. §102

Claims 53-56 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Edwards *et al.* (U.S. Patent No. 5,507,743, hereinafter "the '743 patent").

Claims 57-66 were rejected under 35 U.S.C. §102(e) as allegedly anticipated by Edwards *et al.* (U.S. Patent No. 5,536,267, hereinafter "the '267 patent").

Claims 57-66 were rejected under 35 U.S.C. §102(b) as allegedly anticipated by Edwards *et al.* (U.S. Patent No. 5,370,675, hereinafter "the '675 patent").

These rejections are respectfully traversed.

A. The Present Invention

The present invention describes a method for ablating tissue. The method, according to claim 53 comprises advancing a tissue ablation apparatus comprising an elongated delivery device and at least one RF electrode that is pre-shaped to assume a curved shape and define an ablation volume when deployed. The distal end of the delivery device is positioned in or adjacent the tumorous tissue and the electrodes are deployed. Energy is delivered the selected tissue site through the electrodes to ablate the tissue. The temperature is monitored using at least one sensor positioned on the (at least one) RF electrode, and delivery of the energy is modulated when the temperature reaches a predetermined limit.

The method according to claim 57 comprises positioning an ablation apparatus comprising an elongated delivery device and a plurality of electrodes that are pre-shaped to assume a curved shape and define an ablation volume when deployed. The apparatus

is positioned to place the distal tip of the delivery device in or adjacent the tissue mass. The plurality of electrodes are deployed to define an ablation volume that includes the tissue mass. An ablating current is applied to the deployed electrodes and the tissue mass contained within the defined volume is ablated. A characteristic of the tissue mass is monitored using at least one sensor positioned on at least one of the electrodes as the tissue mass is being ablated. The extent of ablation is controlled in response to the characteristic detected.

B. The Prior Art

EDWARDS ET AL. (5,507,743) The instant application claims priority under 35 U.S.C. §120 at least from Application Serial No. 08/290,031, filed August 12, 1994, now U.S. Patent No. 5,536,267. Accordingly, Applicants submit that the Edwards *et al.* U.S. Patent No. 5,507,743 reference is not an effective document under 35 U.S.C. § 102 or § 103.

EDWARDS ET AL. (5,536,267) The instant application claims priority under 35 U.S.C. §120 at least from Application Serial No. 08/290,031, filed August 12, 1994, now U.S. Patent No. 5,536,267. Accordingly, Applicants submit that the Edwards *et al.* U.S. Patent No. 5,536,267 reference is not an effective document under 35 U.S.C. § 102 or § 103.

EDWARDS ET AL. (5,370,675) describe a medical probe device for treatment of the hyperplastic tissues of the prostate to treat benign prostatic hyperplasia. The probe comprises a catheter having a stylet guide housing for directing a flexible stylet out of the catheter and into the tissue. The catheter is advanced through ducts adjacent to the desired treatment area. The stylet is advanced out of the catheter to penetrate the urethral wall to penetrate the prostate.

C. Analysis

1. Legal Standard

According to the M.P.E.P. § 2131, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference".

2. Rejection over Edwards et al. the '743 patent

In light of the claim to priority under 35 U.S.C §120, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §102(e).

3. Rejection over Edwards et al. the '267 patent

In light of the claim to priority under 35 U.S.C §120, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §102(e).

4. Rejection over Edwards et al. the '675 patent

Edwards *et al.* fail to teach that the plurality of RF electrodes are pre-shaped to assume a curved shape when deployed.

As best seen in figure 4, the stylet of Edwards *et al.* is deployed from the catheter at an angle determined by the stylet housing and does not alter direction from the housing angle. The stylet is not pre-shaped to assume a curved shape when deployed as in the present invention.

Accordingly, Applicants submit that standard of strict identity to maintain a rejection under 35 U.S.C. § 102 has not been met. Withdrawal of the rejections under 35 U.S.C. § 102 is respectfully requested.

V. Rejections under 35 U.S.C. §103

Claims 53-56 was rejected under 35 U.S.C. §103 as allegedly obvious over Edwards et al. (U.S. Patent No. 5,472,441, hereinafter the '441 patent) or the '597 patent in view of the '675 patent.

Claims 53-56 was rejected under 35 U.S.C. §103 as allegedly obvious over either the '675 patent or the '267 patent in view of LeVeen et al. (U.S. Patent No. U.S. Patent No. 5,827,276).

These rejections are respectfully traversed.

A. The Present Invention

The present invention is described above.

B. The Prior Art

EDWARDS ET AL., THE '675 PATENT is described above.

EDWARDS ET AL., THE '597 PATENT The instant application takes priority from Application Serial No. 08/148,439, filed November 8, 1993, now U.S. Patent No. 5,458,597. Accordingly, Applicants submit that the Edwards *et al.* U.S. Patent No. 5,458,597 reference is not an effective document under 35 U.S.C. § 102 or § 103. .

EDWARDS ET AL., THE '267 PATENT As noted above, the instant applicant claims priority under 37 C.F.R. §120 from Application Serial No. 08/290,031, filed August 12, 1994, now U.S. Patent No. 5,536,267. Accordingly, Applicants submit that the Edwards *et al.* U.S. Patent No. 5,536,267 reference is not an effective document under 35 U.S.C. § 102 or § 103.

EDWARDS ET AL. (5,472,441) The instant application takes priority from, at least, Application Serial No. 08/148,439, filed November 8, 1993, now U.S. Patent No. 5,458,597. Therefore, the current claims have a priority date of at least November 8, 1993. Accordingly, Applicants submit that the Edwards *et al.* U.S. Patent No. 5,472,441 reference is not an effective document under 35 U.S.C. § 102 or § 103.

LEVEEN ET AL. The instant application takes priority from, at least, Application Serial No. 08/290,031, now U.S. Patent No. 5,536,267, which has a filing date of August

12, 1994. Therefore, the current claims have a priority date of at least August 12, 1994. The LeVeen *et al.* patent has an earliest priority date of March 24, 1995. Applicants submit that the LeVeen *et al.* reference is not an effective document under 35 U.S.C. § 102 or § 103.

C. Analysis

1. Legal Standard

According to the MPEP § 2143, "to establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art references (or references when combined) must teach or suggest all the claim limitations."

2. Rejection over Edwards et al., the '441 patent or Edwards et al., the '597 patent in view of Edwards et al., the '675 patent

As discussed above, Edwards *et al.*, the '441 patent, and Edwards et al., the '597 patent, are not prior art with respect to the current claims and cannot be combined with the '675 patent.

As noted above, the '675 patent fails to teach that the at least one RF electrode that is pre-shaped to assume a curved shape when deployed.

3. Rejection over Edwards et al., the '675 patent or Edwards et al., the '267 patent in view of LeVeen et al.

As discussed above, LeVeen *et al.* and Edwards et al., the '267 patent, are not prior art with respect to the current claims and cannot be combined with the '675 patent.

As noted above, the '675 patent fails to teach that the at least one RF electrode that is pre-shaped to assume a curved shape when deployed.

In view of the above, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §103.

VI. Obviousness-Type Double Patenting Rejection

Claims 53-66 were rejected under the judicially created doctrine of obviousness-type double patenting as being directed to an invention not patentably distinct from claims 1-38 of U.S. Patent No. 5,728,143.

A Terminal Disclaimer prepared in accordance with 37 C.F.R. §1.321(b) and (c) is enclosed. The signed Terminal Disclaimer obviates the above obviousness-type double patenting rejection.

CONCLUSION

In view of the foregoing, Applicants submit that the claim pending in the application are in condition for allowance. A Notice of Allowance is therefore respectfully requested.

The Examiner is invited to contact Applicants' representative at (650) 838-4410 if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

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Date: 2/21/03

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Appl. No. 08/963,239

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the specification:

On page 1, please replace the paragraph starting on line 3 with the following:

This application is a continuation-in-part of U.S. Patent Application No. 08/605,323, filed February 14, 1996, now U.S. Patent No. 5,728,143, which is a continuation-in-part of U.S. Patent Application Serial No. 08/515,379, filed August 15, 1995, now U.S. Patent No. 5,683,384, which is a continuation-in-part of U.S. Patent Application No. 08/290,031, filed August 12, 1994, now U.S. Patent No. 5,536,267 which is a continuation-in-part of U.S. Patent Application No. 08/148,439, filed November 8, 1993, now U.S. Patent No. 5,458,597, [both]each of which are incorporated herein by reference.

On page 5, please replace the paragraph starting on line 1 with the following:

In various embodiments, the apparatus can include each of the antennas coupled to the electromagnetic energy source, only one antenna coupled to the electromagnetic energy source, or more than one antenna coupled to the electromagnetic energy source. The trocar has an outer diameter of no greater than 13 gauge, preferably no greater than 14 gauge, and still more preferably no more than 15 gauge.

On page 13, please replace the paragraph starting on line 4 with the following:

In figure 3, two antennas 16 are each deployed out of trocar distal end 14' and introduced into selected tissue mass 28. Antennas 16 form a plane and the area of ablation extends between the electromagnetic energy delivery surfaces of antennas 16. Trocar 14 can be introduced in an adjacent relationship to selected tissue mass 28. This particular deployment is useful for small selected tissue masses 28, or where piercing selected tissue mass 28 is not desirable. Trocar 14 can be rotated, with antennas 16 retracted in the lumen of trocar 14, and another ablation volume defined between the antennas 16 is created. Further, trocar 14 can be withdrawn from its initial position

adjacent to selected tissue mass 28, repositioned to another position adjacent to selected tissue mass 28, and antennas 16 deployed to begin another ablation cycle. Any variety of different positionings may be utilized to create a desired ablation geometry for selected tissue mass of different geometries and sizes.

On page 13, please replace the paragraph starting on line 17 with the following:

In Figure 4, [three]two antennas 16 are introduced into selected tissue mass 28. The effect is the creation of a substantially complete ablation volume formed between antennas 16 with a minimal central core that is not ablated.

In the claims:

53. (Twice Amended) A method of volumetric ablation of tumorous tissue, comprising:

providing a tissue ablation apparatus comprising an elongated delivery device having a tissue piercing distal end and a proximal end, and at least one RF electrode having a tissue penetrating distal portion, said at least one RF electrode [has a non-deployed state when positioned inside said delivery device and a deployed state, in which said distal portion of said RF electrode exhibiting a curvedly changing direction of travel as the RF electrode is being advanced from the delivery device into a selected tissue site]is pre-shaped to assume a curved shape and define an ablation volume when deployed;

advancing the elongated delivery device to the selected tissue site [by piercing with said tissue piercing distal end], wherein said advancing is effective to place the distal end of the delivery device in or adjacent the tumorous tissue;

deploying [the]said at least one RF electrode [into the selected tissue site to define an ablation volume];

delivering energy [from the energy delivery device] to [the]a selected tissue site through said at least one RF electrode[s] to ablate said tissue;

monitoring a temperature of said tissue using at least one sensor[s] positioned on said at least one RF electrode; and

[ceasing]modulating delivery of said energy [delivery] when said [measured] temperature reaches a predetermined limit.

56. (Amended) The method of claim 53, wherein said at least one sensor[s are]is positioned at said distal [portion]end of said at least one RF electrode[s].

57. (Twice Amended) A method of ablating a tissue mass comprising:

[providing]positioning in a patient an ablation apparatus comprising an elongated delivery device and a plurality of [antennas conductively coupled to an energy source]electrodes that are pre-shaped to assume a curved shape and define an ablation volume when deployed, wherein said positioning is effective to place the distal tip of the delivery device in or adjacent the tissue mass;

[positioning said antennas adjacent to a target tissue mass, wherein adjacent distal ends of said antennas define an ablation volume;]

deploying said plurality of electrodes, thus to define an ablation volume that includes the tissue mass;

[delivering energy at a sufficient level which is capable of ablating said target tissue mass to said antennas]applying an ablating current to the deployed electrodes, wherein said tissue mass contained within the defined volume is ablated;

monitoring [temperature]a characteristic of said tissue mass using at least one sensor[s] positioned on at least one of said [antennas]electrodes as said tissue mass is being ablated; and

[ceasing said delivery of energy when said measured temperature reaches a predetermined limit]controlling the extent of ablation in response to the characteristic detected at said at least one sensor.

58. (Amended) The method of claim 57 wherein said sensors are positioned at [said]a distal end of said [antennas]electrodes.

59. (Amended) The method of claim [58]71 further comprising adjusting, in response to said [measured temperature]monitored characteristic, said energy [level] to maintain said [temperature]characteristic at a desired value.

60. (Amended) The method of claim [59]57 further comprising infusing said tissue with an infusion medium.

64. (Amended) The method of claim 63, wherein at least one of said plurality of [antennas]electrodes includes a lumen capable of being operatively coupled to an infusion source, and said method further includes infusing a liquid through said electrodes into the defined ablation volume prior to or during said ablating step.

65. (Amended) The method of claim 59, wherein said energy source is a RF source and said [antenna]electrode is a RF electrode.

66. (Amended) The method of claim 65, wherein said [deployed antennas]electrodes, when deployed, have an electromagnetic energy delivery surface of a size sufficient to create a volumetric ablation without impeding out any one of said deployed [antennas]electrodes when 5 to 200 watts of electromagnetic energy is delivered.